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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,524	02/11/2002	Jeremy Emken	P873 US	6764
28390	7590	09/07/2004	EXAMINER	
MEDTRONIC VASCULAR, INC. IP LEGAL DEPARTMENT 3576 UNOCAL PLACE SANTA ROSA, CA 95403			MARMOR II, CHARLES ALAN	
			ART UNIT	PAPER NUMBER
			3736	5

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/074,524	Applicant(s) EMKEN ET AL.	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-9,13,15-18,22 and 23 is/are rejected.
- 7) ☐ Claim(s) 5,10-12,14 and 19-21 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>02112002</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because in lines 6-10, the last two sentences of the abstract do not describe the present invention and should be deleted. Correction is required. See MPEP § 608.01(b).

Claim Objections

2. Claim 10 is objected to because of the following informalities: in line 2, a period should be inserted following "line". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 6, the claim language renders the claim indefinite. It is unclear from the claim language whether Applicant intends to claim a plurality of wire-forms or merely a single wire-form that is adapted to be disposed about a catheter with at least one additional wire-form. The claim positively recites only a single wire-form that is suited for use in conjunction with at least one additional wire-form, but a relationship between a plurality of wire-forms is also recited

in the claim. The "at least one additional wire-form" is never positively recite as part of the apparatus.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Stefanadis et al. ('300). Stefanadis et al. teach an apparatus that radially centers a catheter 1 in a lumen of a body vessel. The apparatus is capable of being used with a brachytherapy catheter for centering a treatment region of the catheter in the body lumen. The apparatus includes a monofilament wire-form 9 having proximal and distal ends; an expanded configuration preformed with multiple lobes 3 arranged in a radially symmetrical staggered sequence along the center line of the catheter 1 (Fig. 2); and a collapsed configuration formable compactly about the center line by drawing apart the wire-form proximal and distal ends (Fig. 1). Each lobe extends from the center line to an apex engageable with the lumen of the body vessel (Fig. 3). The wire-form, when in the expanded configuration, is capable of having a length sufficient to extend over the treatment region of a brachytherapy catheter. The wire-form proximal and distal ends are attachable to the catheter 1. The expanded configuration of the wire-form includes a distal portion of the wire-form. The distal portion is capable of having a length sufficient to extend over a treatment region of the catheter. The wire-form further includes a proximal portion

Art Unit: 3736

extending from the distal portion at least to a proximal end of the catheter (Fig. 5). The proximal portion forms an actuator filament partially disposed within the catheter shaft that is capable of drawing the wire-form proximal end away from the wire-form distal end (Fig. 5). The lobes are generally disposed in at least two radial directions extending through the center line and have shapes that are generally semi-circular or semi-elliptical.

7. Claims 1-4, 8, 9, 13, 15-18, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Gambale et al. ('339). Gambale et al. teach a catheter apparatus capable of brachytherapy treatment of a lumen of a body vessel. The apparatus includes an elongate flexible shaft **125,225** having a radiation source **124,224** located within a distal treatment region; an actuator element **106,206** slidably disposed along the shaft; and a monofilament wire-form **126,226** for centering the treatment region within the lumen. The monofilament wire-form includes a distal end coupled to the distal end of the shaft; a proximal end coupled to the distal end of the actuator; an expanded configuration preformed with multiple lobes arranged in a radially symmetrical staggered sequence along the center line of the catheter (Fig. 6 and 8); and a collapsed configuration formable compactly about the center line by drawing apart the wire-form proximal and distal ends (Fig. 5 and 7). Each lobe extends from the center line to an apex capable of engaging with the lumen of the body vessel. The wire-form, when in the expanded configuration, has a length sufficient to extend over the treatment region of the catheter. The wire-form proximal and distal ends are attachable to the catheter. The expanded configuration of the wire-form includes a distal portion of the wire-form. The distal portion has a length sufficient to extend over a treatment region of the catheter. The wire-form further includes a

Art Unit: 3736

proximal portion extending from the distal portion at least to a proximal end of the catheter (Figs. 5-8). The actuator includes a tubular sleeve 106,206 and a filament partially disposed within the sleeve. The lobes are generally disposed in at least two radial directions extending through the center line and have shapes that are generally semi-circular or semi-elliptical.

An embodiment (Figs. 7 and 8) includes at least one additional wire-form adapted for radially centering a treatment region of a catheter in a lumen, such that a conjunction of the wire-forms has a radially symmetrical sequence of lobes staggered along the distal treatment region.

Allowable Subject Matter

8. Claims 5, 10-12, 14 and 19-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 6 and 7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 5-7 and 14, no prior art of record teach or fairly suggest a centering monofilament wire-form, as claimed by Applicant, where the expanded configuration of the wire-form includes multiple lobes arranged in a radially symmetrical staggered sequence and generally disposed in one plane extending through the center line of the catheter.

Art Unit: 3736

Regarding claims 10-12 and 19-21, no prior art of record teach or fairly suggest a centering monofilament wire-form, as claimed by Applicant, where the expanded configuration of the wire-form includes multiple lobes arranged in a radially symmetrical staggered sequence along the center line of the catheter, and where each lobe has starting and ending segments that are at least partially wrapped around the center line.

Conclusion

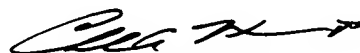
11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fogarty et al. ('130) teach a catheter with a helical balloon at a distal end thereof. Kamdar et al. ('652) teach a device for delivery of a uniform and controlled radiation dose to blood vessels. Liprie ('952) teaches a centering catheter used for the treatment of stenosis.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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August 30, 2004